

REMARKS

Claims 2-4, 6-9, 11, 12, and 14-43 are in the application. All the claims stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Penners et al in view Maggi et al.

In support of this rejection the Examiner has stated that it would be obvious to one skilled in the art to combine the teachings of Penners et al and Maggi et al to arrive at the instant invention. The rejection is respectfully traversed and reconsideration thereof is requested.

Applicants' claimed compositions contain a swelling hydrophilic polymer matrix which consists of a hydrophilic polymer selected from certain specified families of hydrophilic polymers, or a mixture of hydrophilic polymers selected from within the same polymer family. The primary reference relied upon by the Examiner, Penners et al, U.S. Patent No. 5,651,985, describes compositions containing, as gel-forming agent, a mixture of polymers containing lactam groups and polymers containing carboxyl groups, i.e., a mixture of polymers selected from different polymer families. However, Penners et al clearly state at column 7, lines 20-21, that gels are only formed if both polymeric components are present. Pure PVP (a polymer containing lactam groups) is not a stable gel-forming agent. Likewise, Comparison Example 4 shows that carboxymethylcellulose and polyacrylate (polymers containing carboxyl groups) alone have poor mechanical properties, are strongly sensitive to erosion, and are deformed irreversibly even with low mechanical stress. Accordingly, Penners et al teach that a mixture of specific polymers selected from different polymer families is essential to operability, and the reference therefore actually teaches away from Applicants' compositions which require a single polymer or a mixture of polymers selected from the same polymer family.

The secondary reference relied upon by the Examiner, Maggi et al WO 98/08515, fails to cure the inadequacies of the primary reference, Penners et al. Maggi et al disclose multi-layer alfuzosin-containing tablets, at least one of which layers acts as a barrier to the passage of alfuzosin. Again, this reference fails to mention a carbon-dioxide generating system, as required by Applicants' claims. Although Maggi et al do not state that a combination of polymers from different polymer families is necessary, one of ordinary skill in the art would not be motivated to pick from the lengthy list of polymers and families of polymers and limit the compositions to a single polymer or a mixture of polymers from a single polymer family, as required by

Applicants' claims. To the contrary, when viewing the reference as a whole, Maggi et al tend to teach away from the instant invention. Maggi et al encourage the use of "hydrophilic products and/or excipients" which are capable of promoting wetness. These products include crosslinked polyvinylpyrrolidone, hydroxypropylcellulose, hydroxypropylmethylcellulose, crosslinked sodium carboxymethylcellulose, carboxymethyl starch, and divinylbenzene/potassium methacrylate copolymer. Although Maggi et al refer to this list of polymers as "super disintegrating" agents, they are in fact additional hydrophilic polymers included in the disclosed compositions. Each example of a composition provided by Maggi et al includes the use of two different polymers from two different polymer families, one of which may also be used as a hydrophilic product. There is no disclosure in this reference of an actual example in which a composition contains only a single polymer or a mixture of polymers from a single polymer family. Nowhere does Maggi et al provide any suggestion as to how its combination with Penners et al would lead to Applicants' compositions, except perhaps by viewing the references retrospectively in the light of Applicants' disclosure.

The Examiner has urged that one skilled in the art would have been motivated to combine the teachings of Penners et al and Maggi et al on the basis of the holding in *In re Kerkhoven* (205 USPQ 1069.). It is again submitted that Kerkhoven is inappropriate to the instant fact situation and the Examiner's reliance thereon is misplaced. The relevant claims at issue in Kerkhoven were directed to a method of producing particulate detergent compositions containing a mixture of anionic and nonionic detergents by mixing an independently spray-dried anionic detergent with an independently spray-dried nonionic detergent. The court held that it was *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. That is clearly not the situation in the present case.

Applicants have not combined two compositions known for the same purpose in order to achieve a third composition which is to be used for the same purpose. Applicants have discovered a pharmaceutical composition comprising a carbon-dioxide generating system in a swelling hydrophilic polymer matrix which consists of a hydrophilic polymer selected from certain specified families of hydrophilic polymers, or a mixture of hydrophilic polymers selected from within the same polymer family. Combining the compositions of Penners et al and Maggi et al would presumably give a product containing two different compositions each acting

independently; but it would not, and in fact could not, give Applicants' claimed composition. Applicants have discovered that the combination of active ingredients with admittedly known excipients, in a previously unknown manner surprisingly provides compositions having desired and previously unattainable controlled release characteristics with such excipients.

The Examiner appears to have selected from the cited references only so much as will support his position while ignoring what the references as a whole fairly teach one skilled in the art. It is submitted that this picking and choosing from the references amounts to an impermissible hindsight reconstruction of the claimed invention in the light of Applicants' own disclosure. The references, viewed by themselves and not in retrospect once Applicants' disclosure is known, must suggest doing what Applicants have done. It is submitted that the cited references, viewed by themselves at the time the instant invention was made and considered as a whole for what they fairly teach to one skilled in the art, would not have suggested Applicants' invention, and accordingly, the rejection based thereon should be withdrawn.

There being no remaining issues, this application is believed in condition for favorable reconsideration and early allowance and such actions are earnestly solicited.

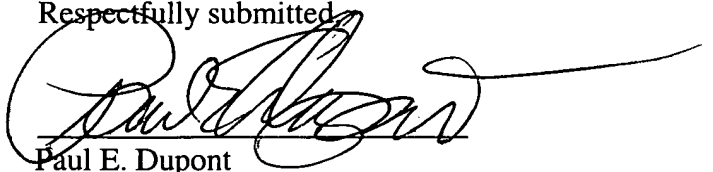
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Respectfully submitted,



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